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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

NEKTAR THERAPEUTICS,

Plaintiff,

vs.

ELI LILLY & CO.,

Defendant.

CASE NO. 3:23-CV-03943-JD

FIRST AMENDED COMPLAINT

1. BREACH OF CONTRACT

2. BREACH OF THE COVENANT OF GOOD FAITH AND FAIR DEALING

DEMAND FOR JURY TRIAL

Plaintiff Nektar Therapeutics ("Nektar") submits this First Amended Complaint against Defendant Eli Lilly and Company ("Lilly") and alleges as follows:

INTRODUCTION

1. This case involves the all-too-familiar story of a large pharmaceutical company elevating profits over all else. Lilly, one of the largest pharmaceutical companies in the world, shirked its clinical and contractual responsibilities to its joint development partner, San Francisco-based Nektar. Nektar had developed a promising new biologic therapy candidate called rezpegaldesleukin ("REZPEG") to treat a host of autoimmune diseases. After entering into the joint development agreement with Nektar regarding REZPEG and committing to spearhead its development, Lilly purchased another company with a competing drug candidate that was also under development. Thereafter, Lilly executed on a scheme to ensure that REZPEG would never succeed.

2. First, Lilly botched the REZPEG data analysis of early clinical trials it conducted under the partnership, which Nektar has only recently discovered resulted in false and inaccurate clinical results being reported. Then, Lilly delayed the development and commencement of additional trials for REZPEG by creating clinically unreasonable trial designs and fabricating excuses for why the drug was not likely to be a commercial success. Lilly's scheme was designed to justify its eventual termination of the parties' agreement, avoid significant payments due to Nektar thereunder, and tarnish REZPEG, thereby delaying or preventing its introduction into the market to compete against Lilly's newly-acquired drug candidate.

3. Lilly's misconduct, including its botched clinical trials data analysis and the subsequent publication of false information, hid REZPEG's true promise. Corrected calculations of the clinical trial data show an impressive ***83% efficacy*** in treating eczema after only 12 weeks of therapy, and an excellent safety profile—efficacy and safety data that support REZPEG's potential to overtake the most popular biologic eczema therapy. But Lilly's misconduct severely tarnished REZPEG. Its development has been stunted and delayed, and the threat of competitor drugs in development looms large.

4. Nektar thus brings this lawsuit to vindicate its legal rights to ensure that it receives fair compensation and obtains appropriate remedies for Lilly's misconduct designed ultimately to eliminate a competing drug (REZPEG) from the market.

THE PARTIES

5. Plaintiff Nektar is a corporation organized under the laws of Delaware with its principal place of business at 455 Mission Bay Boulevard South, San Francisco, California 94158. Nektar is a biopharmaceutical company committed to the discovery and development of new drug therapies. Nektar currently focuses on developing drugs that modulate the body's immune system to treat autoimmune disorders.

6. On information and belief, Defendant Lilly is a corporation organized under the laws of Indiana with its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

JURISDICTION AND VENUE

7. The Federal District Court for the Northern District of California has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 because the matter in controversy exceeds the sum or value of $75,000 and is between citizens of different States. The Court has personal jurisdiction over Lilly because Lilly has committed acts in this District that give rise to Nektar's claims of Breach of Contract, Breach of the Implied Covenant of Good Faith and Fair Dealing, Negligent Misrepresentation, and Unfair Competition Under Cal. Bus. & Prof. Code Section 17200. In addition, Lilly has substantial, systematic, and continuous contacts with this District and regularly conducts business in this District.

8. Venue is proper in the Federal District Court for the Northern District of California pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to Nektar's claim occurred in this District and Lilly is subject to the Court's personal jurisdiction in this District. In addition, venue is proper because Nektar's principal place of business is in this District, and Nektar has suffered harm in this District.

FACTUAL BACKGROUND

Autoimmune Disorder Therapeutics

9. Autoimmune illnesses are brought on by an autoimmune reaction that targets cells and destroys body tissue. More than 80 autoimmune disorders have been identified, including systematic lupus erythematosus ("SLE," the most common form of lupus), ulcerative colitis, and dermatological disorders such as psoriasis and atopic dermatitis. Today, autoimmune disorders are nearly incurable and affect over 300 million people worldwide.[1]

10. Currently available therapeutics for the treatment of autoimmune diseases are often broadly acting, non-disease specific, and, consequently, associated with deleterious side effects. Many patients do not respond optimally to these treatments, if they respond at all. New autoimmune disorder therapeutics are therefore urgently needed.[2] Although estimates of this multibillion dollar market vary, the market has increased dramatically as new therapies having novel mechanisms of action have emerged.

11. Biologics have proven to be effective to treat a variety of autoimmune disorders. For example, the antibody belimumab (Benlysta®) was the first FDA-approved biologic for SLE.[3] A variety of biologics have been approved to treat adult psoriasis (among other indications), including

[1] *At 12.9% CAGR, Global Autoimmune Disease Therapeutics Market Size & Share to Surpass USD 113.48 Billion by 2028*, Bloomberg (July 26, 2022), https://www.bloomberg.com/press-releases/2022-07-26/at-12-9-cagr-global-autoimmune-disease-therapeutics-market-size-share-to-surpass-usd-113-48-billion-by-2028-industry.

[2] Fugger et al., *Challenges, Progress, and Prospects of Developing Therapies to Treat Autoimmune Diseases*, 181 Cell 63-80 (2020).

[3] Yang et al., *A Comprehensive Review of Biological Agents for Lupus: Beyond Single Target*, 11 Frontiers Immunol. 1-11 (2020).

Humira®, Enbrel®, and Stelara® to name a few.[4] Each of these drugs currently generates more than a billion dollars a year in sales—and in the case of Humira®, over $21 billion in 2022 alone.[5]

12. One autoimmune disorder is atopic dermatitis, commonly known as eczema. Over 31 million people (10%) in the United States have some form of eczema, and scientists have estimated that 1 in 10 individuals will develop eczema during their lifetime. An estimated 16.5 million U.S. adults (7.3%) suffer from eczema, with nearly 40% affected with moderate to severe forms of the disease.[6]

13. Mild cases of eczema can sometimes be treated with lifestyle changes and topical drugs and ointments such as corticosteroids. When these treatments are ineffective, more aggressive therapies are often used. In particular, Dupixent® (known generically as dupilumab), developed by pharmaceutical companies Sanofi and Regeneron Pharmaceuticals, currently leads the market in the treatment of moderate to severe eczema. Dupixent® is a biologic drug (antibody) that is injected under the skin. Dupixent® is believed to suppress immune activity and inflammation by blocking signals in the body associated with the molecules interleukin-4 and interleukin-13.

14. Nektar's REZPEG (also known as NKTR-358 and later LY3471851) is a candidate therapy for autoimmune disorders, including eczema. REZPEG is a biologic (a derivative of the molecule interleukin-2) that is injected under the skin. It is believed to regulate immune activity and inflammation and restore balance in the immune system by prolonging the natural immunoregulatory activity of interleukin-2 (IL-2). Its promise was recognized early on by Lilly and other potential development partners. In early studies, Nektar showed that REZPEG "delivers sustained, preferential activation of" regulatory T cells—cells which suppress immune system

[4] *Psoriasis Treatment: Biologics*, Am. Acad. Dermatology Ass'n, https://www.aad.org/public/diseases/psoriasis/treatment/medications/biologics.

[5] *The final hurrah? Humira sales hits $21.2 bn in 2022*, BioProcess Int'l (Feb. 15, 2023), https://bioprocessintl.com/bioprocess-insider/global-markets/the-final-hurrah-humira-sales-hits-21-2-bn-in-2022/.

[6] *Eczema Stats*, Nat'l Eczema Ass'n, https://nationaleczema.org/research/eczema-facts.

activity and regulate the body's immune response to itself.[7] REZPEG's immunoregulatory effect was sustained in primate studies for more than 14 days.

15. REZPEG's unique IL-2-based mechanism of action offers potential advantages to patients suffering from various immunological disorders. In the case of eczema treatment, for example, because REZPEG has a different mechanism of action than Dupixent®, REZPEG has the potential to treat patients who do not respond to Dupixent® therapy.

Nektar-Lilly Partnership Under the 2017 Agreement and Early REZPEG Development

16. After a beauty contest, Nektar selected Lilly to be its joint development partner for REZPEG development. Nektar had solicited partnership opportunities for REZPEG development from other large pharmaceutical companies but ultimately chose Lilly, based on Lilly's representations regarding its extensive drug development capabilities, know-how, and expertise in the field of immunology and biologic therapeutics. In partnering with Lilly, Nektar believed Lilly's experience and immense resources in the field of immunology with development of autoimmune therapies and biologics would provide the best opportunity for REZPEG to be approved for use.

17. On or about July 23, 2017, Nektar and Lilly entered into a license agreement ("Agreement") to collaborate on the development of REZPEG. REZPEG was Nektar's lead autoimmune drug candidate at the time Nektar and Lilly entered into the Agreement. Lilly recognized REZPEG's significant therapeutic potential from Nektar's pre-clinical and first-in-human clinical studies and believed REZPEG was likely to be a successful autoimmune therapeutic, announcing that "NKTR-358 [REZPEG] is an exciting addition to our immunology portfolio and reinforces Lilly's commitment to sustain a flow of innovative medicines in our pipeline."[8]

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[7] Langowski et al., *NKTR-358: a selective, first-in-class IL-2 pathway agonist, which increases number and suppressive function of regulatory T cells for the treatment of immune inflammatory disorders* (2017), https://www.nektar.com/application/files/6315/1001/4171/NKTR-358_2017ACR_ABS2715.pdf.

[8] *Lilly and Nektar Therapeutics Announce Alliance to Develop and Commercialize NKTR-358, A Novel Autoimmune Therapy* (July 24, 2017), https://investor.lilly.com/news-releases/news-release-details/lilly-and-nektar-therapeutics-announce-alliance-develop-and.

REZPEG's potential was not limited to eczema therapy, and the parties contemplated developing REZPEG for use in other indications such as lupus and psoriasis.

18. Under the Agreement, after an initial development phase, Lilly undertook full responsibility for the continued clinical development of REZPEG, with the understanding that Lilly would commercialize REZPEG if its development succeeded. *See* Agreement Introduction A-C & § 3.7(c). Lilly committed to "act[ing] in good faith, using Commercially Reasonable Efforts, to perform [Lilly's] assigned tasks and responsibilities as described in the Product Development Plan" for REZPEG. *See* Agreement § 4.1. Lilly was also obligated to "use Commercially Reasonable Efforts to conduct all Product development activities only in the Field from the conclusion of the Initial Development Phase, including all remaining pre-clinical and clinical testing necessary or useful for developing Product and the preparation and submission of the appropriate regulatory documents required for commercialization of Products in the Field and in the Territory." *Id.* § 4.5. Lilly was also obligated to "use Commercially Reasonable Efforts to develop, receive Regulatory Approval for, market and sell at least one Product in the Field in the Major Markets." *Id.* § 4.9.

19. At all times under the Agreement and prior to its termination, Lilly was obligated to act in good faith using "Commercially Reasonable Efforts" in REZPEG development. Article I of the Agreement defines "Commercially Reasonable Efforts" as follows:

> "**Commercially Reasonable Efforts**" or "**CRE**" means effort, expertise and resources normally used by the Party in the development and/or commercialization of a comparable pharmaceutical product Controlled by such Party which is of similar market potential at a similar stage of development or commercialization in light of issues of safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory structure involved, the profitability of the applicable products, product reimbursement and other relevant strategic and commercial factors normally considered by the Party in making product portfolio decisions. For purposes of clarity, Commercially Reasonable Efforts will be determined on an Indication-by-Indication and country-by-country basis within the Territory, and it is anticipated that the level of effort may be different for different Indications and countries and may change over time, reflecting changes in the status of the Product and the Indications and country(ies) involved.

20. In the Agreement, Lilly also agreed to engage in "Good Research Practices," which included in its definition the effort, expertise and resources normally used by Lilly in the

development and/or commercialization of drug candidates. Article I of the Agreement defines "Good Research Practices" as follows:

> "**Good Research Practices**" or "**cGRP**" means all applicable current Good Research Practices including, as applicable, (a) the research quality standards defining how Lilly's research laboratories conduct good science for non-regulated work as set forth in **Schedule 4.8 Part A** of this Agreement, (b) the Research Quality Association (RQA), 2014 Quality in Research Guidelines for Working in Non-Regulated Research, (c) the WHO Quality Practices in Basic Biomedical Research Guidelines and (d) the equivalent applicable laws if any, in any relevant country, each as may be amended and applicable from time to time.

21. Schedule 4.8, Part A, of the Agreement sets forth Lilly's Good Research Practices which are "Lilly's quality standards, along with the high level expectations for each standard." As defined in Schedule 4.8, Part A, of the Agreement, Lilly's Good Research Practices include:

> 3. **Personnel**
> Personnel for Study are qualified and can perform Study tasks to meet expectations (e.g., curriculum vitae, training records, education records, experience, etc.).
>
> 8. **Record / Data / Notebook Management**
> Data is managed to ensure accuracy, completeness and retrievability.
>
> 9. **Reports**
> All data included in reports must be reviewed to ensure that the reports accurately reflect the data.
>
> 12. **Quality Systems**
> Mechanisms exist to help personnel clearly understand their roles and responsibilities (e.g., work instructions, guidance documents, work plans, protocols, requirements, SOPs).
> Quality Control processes exist to show specifications are met.

22. By including Lilly's Good Research Practices in the Agreement, Lilly committed to following its Good Research Practices with respect to REZPEG development.

23. Lilly was also liable to Nektar for any acts or omissions of Lilly's subcontractors under the Agreement, including breaches of Lilly's Good Research Practices. *See* Agreement § 4.10. On information and belief, Lilly engaged at least one subcontractor to conduct the statistical analysis of at least the eczema and psoriasis clinical trials discussed below.

24. The Agreement also provided for "milestone" payments from Lilly to Nektar after certain clinical goals were achieved (the "Milestone Payments"). The first Milestone Payment was

[redacted] for the "[f]irst patient treated by or on behalf of Lilly in a Phase III Study for a Product," *e.g.*, REZPEG. Agreement § 6.2(b). The second Milestone Payment was [redacted] after REZPEG achieved its "first Phase III Study 'success'" under the Agreement. *Id.* The third Milestone Payment was [redacted] after Lilly received an approved Biologic License Application for REZPEG from the FDA. *Id.* The fourth Milestone Payment was [redacted] after Lilly received an approved Biologic License Application for REZPEG from the European Commission. *Id.*

25. [redacted]

26. Lilly initially appeared enthusiastic about REZPEG's therapeutic potential. In discussions with Nektar in the fall of 2017, Lilly's key areas of focus were rheumatology (*e.g.*, lupus), gastrointestinal disorders, and dermatology. At the time, Lilly and Nektar agreed that lupus would be the lead indication for REZPEG. Lilly believed that if REZPEG was "safe and effective for SLE, Lilly feels it could be a game changer for the disease." Over the next several years, Lilly undertook clinical investigation of REZPEG as a lupus treatment in the lupus clinical trial discussed below.

27. Early in 2018, Lilly and Nektar discussed expanding REZPEG development to treat dermatological disorders as "there is a potential commercial benefit if efficacy can be shown in mild/moderate patients." In early evaluations, the "probability of detecting Dupilumab [Dupixent®]-like efficacy" in treating eczema was estimated to be "80%." These efforts resulted in the eczema and psoriasis clinical trials discussed below.

Rise of Dupixent® and Lilly's Dermira Acquisition (2019-2020)

28. In the Fall of 2019, Lilly was preparing to undertake studies of REZPEG as an eczema and psoriasis therapy. At that time, on information and belief, Lilly did not have another autoimmune drug candidate near approval. Lilly had been pursuing a small-molecule (non-biologic)

drug baricitinib as a possible eczema therapy, but the FDA had previously refused to approve baricitinib to treat lupus[9] and was unlikely to approve baricitinib for eczema.[10]

29. Lilly recognized the market opportunity for drugs that treat eczema. Sanofi/Regeneron's Dupixent®, approved in 2017 for the treatment of moderate to severe atopic dermatitis (eczema), was on a trajectory to become a blockbuster drug. Indeed, in or around October 2019, as Lilly was preparing its studies of REZPEG as a dermatological therapy, Sanofi reported publicly that Dupixent® was likely to become a "megablockbuster," generating significantly more than a billion dollars a year in sales.[11] The market has since recognized that Dupixent® "has become a money-printing machine" for its makers, "generating $2.8 billion over the first half of 2021 alone and growing in excess of 50% year on year."[12]

30. On or about January 20, 2020, only a few months after initiating studies of eczema and psoriasis with REZPEG, Lilly purchased Dermira, Inc. for approximately $1.1 billion.[13] At that time, Dermira had developed and was in the process of seeking approval for its antibody lebrikizumab to treat eczema. Prior to acquisition by Lilly, Dermira had investigated lebrikizumab in comparison to Dupixent® in eczema patients. Both drugs' mechanisms of action share significant

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[9] *U.S. FDA Issues Complete Response Letter for Baricitinib* (Apr. 14, 2017), https://investor.lilly.com/news-releases/news-release-details/us-fda-issues-complete-response-letter-baricitinib.

[10] *Eli Lilly, Incyte axe Olumiant in lupus amid eczema stalemate at FDA* (Jan. 28, 2022), https://www.fiercepharma.com/pharma/eli-lilly-incyte-axe-olumiant-lupus-amid-eczema-stalemate-at-fda.

[11] *Dupixent's already a blockbuster, but there's much more to come* (Oct. 31, 2019), https://www.fiercepharma.com/pharma/dupixent-s-already-a-blockbuster-but-there-s-much-more-to-come-sanofi-exec.

[12] *Lilly, swinging at the king, shows Dupixent rival works in phase 3, but wait for key figures goes on* (Aug. 16, 2021), https://www.fiercebiotech.com/biotech/lilly-swinging-at-king-shows-dupixent-rival-works-phase-3-but-wait-for-key-figures-goes.

[13] *Lilly Announces Agreement to Acquire Dermira* (Jan. 10, 2020), https://investor.lilly.com/news-releases/news-release-details/lilly-announces-agreement-acquire-dermira; *Lilly Completes Acquisition of Dermira* (Feb. 20, 2020), https://investor.lilly.com/news-releases/news-release-details/lilly-completes-acquisition-dermira.

similarities, as both Dupixent® and lebrikizumab (both antibodies) are believed to suppress immune activity and inflammation by blocking signals in the body associated with the same inflammatory molecule, interleukin-13. In March 2019, Dermira reported that lebrikizumab produced "symptom improvements comparable to Dupixent's."[14] Lilly is presently seeking approval of lebrikizumab as an eczema treatment.[15]

31. After purchasing lebrikizumab, Lilly's interest and effort in developing REZPEG waned dramatically, as if it had forgotten it had independent and continuing contractual obligations to Nektar to act in "good faith" and "use Commercially Reasonable Efforts to develop, receive Regulatory Approval for, market and sell" REZPEG. Agreement §§ 4.1, 4.9. Around the same time period leading up to reported success in the lebrikizumab trial, Lilly sloughed certain of its development work for REZPEG onto at least one subcontractor. Lilly then failed to properly direct, supervise, review or validate the work of its subcontractor(s). As a result, Lilly botched the analysis of clinical trial data from the studies of REZPEG involving at least eczema and psoriasis as explained below.

32. Lilly's failures were a gross dereliction of its duties under the Agreement. A clinical trial is an extremely important and serious endeavor representing the investment of thousands of man-hours and millions of dollars, in which subjects—often vulnerable or sick patients—are exposed to drugs which may cause harmful and unexpected side effects, requiring tight regulatory

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[14] *Lilly's atopic dermatitis med scores another late-stage win in attempt to outdo Dupixent* (Dec. 21, 2021), https://www.fiercebiotech.com/biotech/lilly-s-atopic-dermatitis-med-scores-another-late-stage-win-attempt-to-outdo-dupixent; *Dermira delivers it to Dupixent* (Mar. 18, 2019), https://www.evaluate.com/vantage/articles/news/snippets/dermira-delivers-it-dupixent ("'The best outcome we could have hoped for' is how Dermira executives described phase IIb data with the atopic dermatitis project lebrikizumab this morning, and investors appeared to agree: shares almost doubled in early trade, putting the group's valuation at $570m. Results suggest that the company's IL-13 antibody has similar efficacy to Sanofi/Regeneron's blockbuster Dupixent, but with a more convenient dosing schedule.").

[15] *Up to 73% of Atopic Dermatitis Patients Taking Lilly's Lebrikizumab Had Improved or Cleared Skin on Face or Hands in New Analysis* (May 1, 2023), https://www.prnewswire.com/news-releases/up-to-73-of-atopic-dermatitis-patients-taking-lillys-lebrikizumab-had-improved-or-cleared-skin-on-face-or-hands-in-new-analysis-301811624.html.

supervision by the FDA. Clinical trial sponsors such as Lilly are therefore obligated to take great care and pay attention to accuracy in the analysis of trial data to ensure patient safety as well as statistically correct reporting of drug efficacy. The proper conduct of clinical trials—including the statistical analysis of study data—is therefore not only commercially reasonable (for example, to justify the enormous expense and effort of a clinical trial), it is absolutely critical to protect patient health.

33. Lilly was required to carefully monitor and accurately report the outcomes of the REZPEG trials. This, Lilly failed to do.

Lilly's Flawed Eczema Study Analysis and False Publication

34. On or about September 2019, Lilly began a Phase 1b study of REZPEG in atopic dermatitis (eczema) patients, titled "A Phase 1, Double-Blind, Randomized, Placebo-Controlled, Multiple-Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Subcutaneous LY3471851 in Patients With Atopic Dermatitis" (study code: J1P-MC-KFAD) (herein "Eczema Study"). The Eczema Study formally began on or about December 4, 2019, and completed on or about June 24, 2022.[16]

35. The Eczema Study was designed to evaluate REZPEG's safety compared to placebo in eczema patients. The study also collected data on REZPEG's therapeutic efficacy using the Eczema Area and Severity Index ("EASI"). The EASI is a well-known, standardized clinical evaluation tool used by physicians for decades to measure eczema using a 72-point scale. As explained in the trial's Statistical Analysis Plan ("SAP"), for example, EASI is a "disease activity measure[]" that "assesses the extent of disease," and a "key clinical assessment is the percentage change from baseline in EASI at Week 12" of therapy.[17]

[16] *A Study of LY3471851 in Participants With Eczema*, https://clinicaltrials.gov/study/NCT04081350.

[17] Eczema Study Statistical Analysis Plan v.2 (Oct. 21, 2022) at 5, 9.

36. To calculate an EASI score on the 72-point scale, a healthcare practitioner assesses eczema in each of four body regions separately (head and neck, upper extremities, trunk, and lower extremities). The practitioner assigns each region an area score based on the involvement of eczema in that area: 1 (1%–9%), 2 (10%–29%), 3 (30%–49%), 4 (50%–69%), 5 (70%–89%), and 6 (90%–100%). The practitioner also evaluates eczema's intensity in each area by measuring erythema (redness), edema/papulation, excoriation, and lichenification, each on a scale of 0 (clear/none) to 3 (severe). These values are scaled with a multiplier that reflects the relative contribution of the respective region to overall body surface area. The product is each individual region's score. Lastly, all four region scores are summed to produce the patient's final EASI score.[18] As noted in the SAP, EASI "confers a maximum score of 72."[19]

Severity Score	Area Score						
Grade each sign on a scale: 0=clear/none 1=mild 2=moderate 3=severe	% Involvement	0	1-9%	10-29%	30-49%	50-69%	70-89%	90-100%
	Area Score	0	1	2	3	4	5	6

EASI Calculator (Adults)							
Body Region	Erythema (0-3)	Edema/ Papulation (0-3)	Excoriation (0-3)	Lichenification (0-3)	Area Score (0-6)	Multiplier	Score
Head/Neck	(+	+	+	)	x	x 0.1	
Trunk	(+	+	+	)	x	x 0.3	
Upper Extremities	(+	+	+	)	x	x 0.2	
Lower Extremities	(+	+	+	)	x	x 0.4	
The final EASI score is the sum of the 4 region scores (0-72):							____

37. The Eczema Study clinicians used the EASI to evaluate patients at each visit during the trial and, on information and belief, used a rubric like the exemplary EASI Calculator above.

[18] Hanifin et al., *The Eczema Area and Severity Index—A Practical Guide*, 33 Dermatitis 187-192 (2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9154300.

[19] Eczema Study Statistical Analysis Plan v.2 (Oct. 21, 2022) at 5, 9.

On information and belief, Lilly subsequently used the clinicians' EASI data to analyze Eczema Study patients' response to REZPEG.

38. Despite Lilly's awareness of the seriousness and importance of proper clinical trial conduct (including the analysis of clinical trial data), Lilly failed to correctly set up its statistical algorithm to evaluate EASI data from the REZPEG trial (the "Botched Math"), a simple and straightforward task—yet a critical one, because human health and safety is on the line when drugs are given to patients. On information and belief, the Botched Math summed the first four EASI boxes for each area—the four intensity factors—but failed to multiply each sum by the respective area score and multiplier.

39. Using the Botched Math, the maximum EASI score that could be achieved was 48—*i.e.*, the sum of each of the four intensity scores in the four regions, with each intensity score having a maximum value of "3." However, the actual maximum EASI score—well-known to practitioners and clinicians in this field—is 72. As a result, using its Botched Math, Lilly incorrectly calculated the EASI scores from the clinical data generated in the study, which resulted in under-reporting important clinical efficacy outcomes, and understating the benefit REZPEG provided to patients who received the drug candidate in the trial.

40. On information and belief, Lilly generated the erroneous EASI scores because Lilly failed to correctly implement the pre-specified SAP for the Eczema Study. It critically failed to supervise and review the implementation of the SAP before, during, and after the trials to confirm that the algorithm being used was correctly reporting REZPEG's therapeutic efficacy against eczema.

41. Lilly's actions were, at a minimum, grossly negligent, if not intentional. Had Lilly acted in accordance with good clinical research practices and in a commercially reasonable manner to verify the statistical algorithm and the EASI scores it generated, the serious flaws in the algorithm and Lilly's calculations would have been obvious and easy to correct prior to publication of the data. Given Lilly's purchase of Dermira and development of lebrikizumab after it had entered into the Agreement with Nektar, Lilly was incentivized to shirk its clinical and contractual responsibilities. It failed to properly direct, supervise or review the work of its subcontractor(s) to whom it had

pawned off the work. Indeed, instead of verifying the results and correcting the serious error—or even providing the underlying raw clinical data to Nektar to enable it to do so—Lilly compounded the serious error with the publication of the botched data to the world, thereby severely undermining REZPEG's prospects.

42. On information and belief, Lilly calculated interim analysis results for the Eczema Study on or about November 2021—at or around the same time Lilly reported favorable Phase 3 results for lebrikizumab. Due to Lilly's use of the Botched Math, however—*i.e.*, failing to use the true 72-point EASI—its analysis significantly underreported REZPEG's true efficacy in the trial (the "Botched Interim Eczema Results").

43. On or about December 2021, Lilly presented the first Botched Interim Eczema Results to Lilly management and investors at an Investor Day presentation. On information and belief, Lilly began strategizing how to make REZPEG fail in its follow-on clinical trial, which would give it "cover" under the Agreement and ensure REZPEG's permanent failure as a drug candidate and therapy for eczema, eliminating it as a competitor to lebrikizumab.

44. Lilly transmitted the results of the Botched Math to Nektar at least on June 13, 2022. On that day, Lilly's Senior Director in the Office of Alliance Management wrote to Nektar's Senior Vice President and Chief Business Officer, and Nektar's Senior Director of CMC Program Management, attaching "final versions of the EADV abstracts[.]" The e-mail attached a document discussing results from the Eczema Study, including the "Percentage change from Baseline" as measured in EASI. These results showed a 65.17% efficacy for REZPEG. This number misrepresented an existing material fact.

45. On or about September 7-10, 2022, Lilly presented the second Botched Interim Eczema Results at the European Academy of Dermatology and Venereology (EADV) Congress, a major international dermatology conference. In an abstract by Schleicher *et al*. titled "Efficacy and Safety of a Selective Regulatory T-Cell Inducing IL-2 Conjugate (LY3471851) in the Treatment of Atopic Dermatitis: A Phase 1 Randomised Study" ("False Eczema Publication"), which contained clinical trial data calculated using the Botched Math, Lilly wrongly reported that REZPEG's anti-

eczema efficacy at the high dose (24 μg/kg) after 12 weeks of treatment was approximately 66%.[20] Lilly also improperly excluded data from two patients at this timepoint.

46. Had Lilly used the correct EASI without the Botched Math for all patients who should have been considered, REZPEG's true anti-eczema efficacy at the high dose would have been shown to be approximately 83%. The False Eczema Publication also failed to correctly report the percentage of patients who responded to high-dose REZPEG. The False Eczema Publication reported that approximately 29% of patients had 75% or greater improvement from their baseline condition (the "EASI75" score) after taking high-dose REZPEG for 12 weeks. The true and accurate percentage of patients taking high-dose REZPEG who had 75% or greater improvement from their baseline condition was materially higher at approximately 41%.

47. This publication of wrong clinical data in the False Eczema Publication materially mischaracterized the results of the Eczema Study and efficacy of REZPEG at a major medical conference to peer scientists. As a result of the False Eczema Publication, market analysts and investors were lukewarm on REZPEG's promise. For example, Stifel reported that the Eczema Study data "received a muted response from investors" because "in AD [eczema], the EASI efficacy profile looks roughly in line with Dupixent at certain time points, but not others" as well as other statistical concerns.[21] Similarly, SVB Securities reported that "these 12-wk assessments [in the Eczema Study] are not yet competitive relative to leading anti-IL-4R / anti-IL-13 biologics (e.g., >30% reductions for dupilumab, lebrikizumab, tralokinumab)."[22]

48. Had Lilly not botched the data analysis, and had REZPEG's true clinical trial efficacy been shown, the market would have responded differently. For example, Phase 2 trials of Dupixent®

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[20] Schleicher *et al.*, *Efficacy and Safety of a Selective Regulatory T-Cell Inducing IL-2 Conjugate (LY3471851) in the Treatment of Atopic Dermatitis: A Phase 1 Randomised Study*, P1242 (2022), https://www.nektar.com/application/files/6416/6249/0362/EADV22_Schleicher_P1242.pdf.

[21] *Nektar Therapeutics: 3Q22 Update: We Don't Expect ASH To Be A Big Event For The Stock, But 1H23 Lupus Data Are Interesting*, Stifel (Nov. 4, 2022).

[22] *Nektar Therapeutics: Rezpeg has Clinical and PD Impact in AtD, but Murky Path Forward*, SVB Securities (Sept. 7, 2022).

and lebrikizumab showed approximately 68% and 72% efficacy after a 16-week treatment period, respectively. REZPEG's Phase 1b 83% efficacy after only 12 weeks would have appeared extremely impressive and competitive in comparison.

49. Nektar had no knowledge of this botched data analysis. Lilly declined to share the underlying raw clinical data with Nektar until after termination of the Agreement, requiring Nektar to rely on Lilly to analyze and report accurate results. Lilly has since conceded that it botched the data analysis from the Eczema Study. Nektar also learned that Lilly deliberately chose to exclude three patients from the interim analysis of the reported False Eczema Publication, even though such patients should have been included, further minimizing REZPEG's true efficacy. Lilly's conduct reflects gross negligence and/or intentional misconduct in the supervision and execution of the Eczema Study.

Lilly's Unreasonable Phase 2 REZPEG Study Design for Eczema

50. After Lilly purchased Dermira and acquired the rights to lebrikizumab in 2020, Lilly began looking for reasons to delay REZPEG's development and focus its efforts on lebrikizumab instead. At that time, Lilly was motivated to delay REZPEG development for multiple reasons, including that it could ensure that its own drug, lebrikizumab, benefited from a significant head start in the development timeline, if not eliminate REZPEG as a competitor entirely. It could also avoid paying Milestone Payments to Nektar for the various clinical "milestones" defined in the Agreement.

51. Lilly had a direct conflict of interest between its desire to develop lebrikizumab as an eczema drug and its contractual obligations to develop REZPEG, also a candidate eczema therapy. Accordingly, on information and belief, Lilly sought to eliminate this conflict not only by impeding and delaying REZPEG's development, but also by taking steps to ensure REZPEG would never be developed at all.

52. By way of example, after never before having expressed serious concerns about "injection site reactions" ("ISRs") for REZPEG, in 2020, Lilly began expressing concerns about ISRs that occurred after administration of REZPEG. These purported concerns resulted from Lilly's interest in ditching REZPEG development rather than genuine concerns about REZPEG safety or

commercial desirability, however. Biologic drugs such as Dupixent®, REZPEG, and many other therapeutic antibodies and fusion proteins are administered either intravenously or under the skin (subcutaneously). And many of Lilly's own approved and best-selling drugs are injectable drugs. Indeed, ISRs are one of the "most common" side effects observed following Dupixent® administration.[23] Despite frequent ISRs associated with Dupixent® therapy, Dupixent® is considered "generally well tolerated, with low rates of serious adverse events and treatment discontinuations due to adverse events."[24]

53. On information and belief, Lilly recognized that an injectable therapy was likely needed to treat moderate to severe forms of eczema (*e.g.*, as had been shown for Dupixent®). Lilly also knew that its own drug, lebrikizumab, which it had just acquired, was also associated with ISRs, including ISRs that are mostly "mild or moderate in severity."[25] Lilly understood that REZPEG likewise could have familiar injectable side effects such as ISRs and that such side effects would be commercially acceptable if REZPEG were shown to be an efficacious eczema treatment.

54. In fact, in clinical testing, REZPEG administration did not result in significant problems associated with injection or ISRs. In early single ascending dose (SAD) and multiple ascending dose (MAD) studies of REZPEG, Nektar reported to Lilly that all ISRs were Grade 1 (the mildest form) and resolved without medical intervention, and that ISRs did not appear to worsen

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[23] Gooderham et al., *Dupilumab: A review of its use in the treatment of atopic dermatitis*, J. Am. Acad. Dermatol. S28-S36 (Mar. 2018) at S34 ("The most common adverse events in all trials were nasopharyngitis, upper respiratory tract infection, injection site reactions, skin infections, and conjunctivitis (see Table I). Injection site reactions were more commonly reported in the treatment groups in all phase III trials. These reactions were generally mild to moderate.").

[24] Frampton & Blair, *Dupilumab: A Review in Moderate-to-Severe Atopic Dermatitis*, 19 Am. J. Clin. Derm. 617-624 (2018) at Abstract.

[25] Gooderham et al., *Injection site reactions from an integrated analysis of phase 2 and phase 3 clinical trials of lebrikizumab treatment in moderate-to-severe atopic dermatitis*, 188 Br. J. Dermatol. (2018) at Abstract ("Overall, a low proportion of patients reported ISRs (<3%) with a numerically higher frequency of LEB-treated patients who reported ISRs compared to placebo (1.5%). Most events were mild or moderate in severity, did not lead to treatment discontinuation, occurred within the first 16 weeks of treatment, and ISRs incidence did not increase with a longer duration of exposure.").

with repeated doses. Thus, Lilly's purported concerns about ISRs were not commercially reasonable or made in good faith, and were instead intended to create a pretext for ceasing REZPEG development in a competing indication.

55. On information and belief, Lilly implemented certain clinical study designs to prospectively search for or solicit a higher ISR rate, which were not industry standard practice for collection of adverse events in clinical studies, for the purpose of intentionally slowing down or discontinuing development of REZPEG.

56. In Spring 2022, after Lilly's generation of the Botched Interim Eczema Results, but before Nektar knew that the clinical trial data analysis had been botched, Lilly and Nektar began discussing the design of a Phase 2 trial for REZPEG. By way of example, on or about June 8, 2022, Lilly provided Nektar with a presentation setting forth Lilly's intended design of the REZPEG Phase 2 trial, titled "IL-2 Conjugate [REZPEG]: Atopic Dermatitis Phase 2B Interim Strategy" ("Eczema Phase 2 Study Plan").

57. In the initial Eczema Phase 2 Study Plan, Lilly proposed including [redacted] "interim" analyses of the study data. [redacted] interim analyses is highly unusual in the conduct of clinical trials in eczema and other autoimmune indications—or in any clinical trial for that matter—and does not reflect either a commercially reasonable design or one proposed in good faith. Indeed, no interim analyses are necessary at all in a clinical trial, particularly in a Phase 2 trial, which is conducted in patient volunteers to confirm the signals of efficacy prior to investing in large Phase 3 trials. In Dermira's Phase 2 trial of lebrikizumab, for example, "[n]o interim analyses were planned or performed."[26]

58. Under Lilly's Eczema Phase 2 Study Plan, by way of example, [redacted] The practical effect of the Eczema Phase 2 Study Plan's design

[26] Guttman-Yassky et al., *Efficacy and Safety of Lebrikizumab, a High-Affinity Interleukin 13 Inhibitor, in Adults With Moderate to Severe Atopic Dermatitis: A Phase 2b Randomized Clinical Trial*, 156 JAMA Dermatol. 411-420 (Feb. 2020).

was to give Lilly an excuse to stop the Eczema Phase 2 Study quickly, based on results from only [redacted]

59. Lilly's approach to the design of a REZPEG Phase 2 trial in eczema was also unreasonable based on the criteria for ending the trial early ("futility"). Under Lilly's design, the study would terminate unless—[redacted]—REZPEG's efficacy was predicted to be ***as good or better*** than t[redacted]This extremely stringent criterion, based on only limited clinical trial efficacy data, was intended for one purpose—to kill REZPEG development as early as possible.

60. Nektar objected to Lilly's Eczema Phase 2 Study Plan with the [redacted]interim analyses as unreasonable. Between summer and winter 2022, Lilly ultimately acknowledged that its design was improper and claimed to be restructuring the Phase 2 trial design. In so doing, Lilly successfully, though needlessly, significantly delayed REZPEG's progression into Phase 2 studies for eczema therapy. In fact, Lilly never even initiated the Phase 2 trial.

61. In an August 2022 meeting with Nektar, Lilly asserted that REZPEG "ISRs seen to date are above and beyond what are typically seen with biologics." This claim was false at least because REZPEG's ISRs were very much in line with existing therapies, both in terms of frequency and grade, and, in any event, the ISRs were mild and had resolved.

62. In an accompanying presentation, Lilly claimed that it had performed "quantitative" market research in 2021 followed by "qualitative" market research in 2022, purportedly showing that ISRs would have "a negative impact on [customer] preference" in eczema and lupus therapy. Highly skeptical of these studies, Nektar told Lilly that it would be "helpful to see the details of the market research results," warning Lilly that a "delay in the start to the Ph2 [Phase 2] study could impact the lead that we currently have relative to other IL-2s." Nektar also "requested to see the top / most frequent reasons for discontinuation and the pooled discontinuation rates" from the clinical studies and suggested that the Eczema Study participants "should be polled to understand ISR impact and build our understanding of risk/benefit." Nektar also raised concerns that Lilly was scoring low-grade ISRs as severe in REZPEG clinical trials.

63. Nektar also pointed out the inconsistency in Lilly's approach to continued REZPEG development, noting that "interim assessments were the key topics of focus before" Lilly's June 27, 2022 Board of Directors meeting, whereas "ISRs appear to be the focus after" that meeting. Lilly attempted to justify its about-face by countering that "there has been a holistic assessment of data seen to date which includes available ISR data." Lilly asserted that "high efficacy" of REZPEG "would be key in helping to offset ISR impact," a disingenuous concern given the actual experience with ISRs in the clinical trial. In any event, had Lilly calculated all the efficacy endpoints in the Eczema Study data correctly, Lilly would have observed REZPEG's potential for "high efficacy," therefore satisfying its disingenuous concern.

Lilly's Flawed Psoriasis Study Analysis

64. Lilly's lack of care, attention, and oversight for the REZPEG trial analyses led Lilly to botch the data analysis for a ***second*** indication being researched for REZPEG—this time, in psoriasis patients—in the same way that it botched the Eczema Study results. This psoriasis study was just as important and serious an endeavor as a potential proof of concept of efficacy in a skin disease, and required the same careful attention to trial analysis as the Eczema Study. Lilly failed to act in a commercially reasonable fashion to ensure that it properly analyzed the psoriasis study data and that the clinical data assessments in the trial were conducted correctly consistent with Lilly's clear legal obligations to do so.

65. Psoriasis, like eczema, is an autoimmune skin disorder. The severity of psoriasis and patients' treatment response can be measured using the Psoriasis Area and Severity Index ("PASI"). The PASI is as well-known and simple to use as the EASI, and, as the EASI is based on the PASI, both tests use a 72-point scale as discussed above.

66. Beginning on November 26, 2019, Lilly oversaw a Phase 1(b) study of REZPEG in psoriasis patients, titled "A Phase 1, Double-Blind, Randomized, Placebo-Controlled, Multiple-Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Subcutaneous LY3471851

in Patients With Psoriasis" (study code: J1P-MC-KFAC) (the "Psoriasis Study").[27] The Psoriasis Study was designed to evaluate REZPEG's safety compared to placebo when injected under the skin of psoriasis patients. The Psoriasis Study completed on or about July 21, 2021.

67. Similar to the Eczema Study, Lilly collected REZPEG efficacy data in the Psoriasis Study using PASI. Lilly's calculation of PASI scores in the Psoriasis Study was fundamentally flawed. On information and belief, Lilly's calculations relied on the same error as in the Botched Math to calculate PASI data in the Psoriasis Study—a fact that Nektar did not discover until mid-2023, after the termination of the parties' Agreement and Nektar's receipt of the raw clinical study data. Indeed, in August 2023, Lilly admitted to Nektar that it used the same kind of Botched Math with the Psoriasis Study as it did with the Eczema Study.

68. On information and belief, Lilly generated the erroneous data because Lilly failed to correctly implement the pre-specified SAP for the Psoriasis Study. It critically failed to supervise and review the implementation of the SAP before, during, and after the trials to confirm that the calculation was correctly reporting REZPEG's therapeutic efficacy against psoriasis.

69. After failing to verify the results and correcting the serious error, Lilly had the botched data published to the world at the EADV Congress on or about September 7-10, 2022, in an abstract by Forman *et al.* titled "Efficacy and Safety of a Selective Regulatory T-Cell Inducing IL-2 Conjugate (LY3471851) in the Treatment of Psoriasis: A Phase 1 Randomised Study" ("False Psoriasis Publication").[28] Due to Lilly's use of the Botched Math and failure to meet the most basic standard of clinical care let alone commercially reasonable efforts, however, although the False Psoriasis Publication purportedly showed the final data from the Psoriasis Study, it underreported REZPEG's true therapeutic efficacy against psoriasis. For example, had Lilly reported REZPEG's true efficacy in the Psoriasis Study, it would be known that 21% of patients receiving REZPEG

[27] *A Study of LY3471851 in Participants With Psoriasis*, https://clinicaltrials.gov/study/NCT04119557.

[28] Forman *et al.*, *Efficacy and Safety of a Selective Regulatory T-Cell Inducing IL-2 Conjugate (LY3471851) in the Treatment of Psoriasis: A Phase 1 Randomised Study*, P1611 (2022), https://www.nektar.com/application/files/1916/6249/0362/EADV22_Forman_P1611.pdf.

achieved 75% or greater improvement from their baseline condition (a "PASI75" score)—not the mere 11% of responders reported in the False Psoriasis Publication. Such results were not just wrong, they revealed a reckless disregard for good science and for Lilly's obligations to develop REZPEG in a commercially reasonable manner.

Lilly's Flawed Lupus Study Conduct and Analysis

70. Although initially excited about REZPEG's prospects as a lupus therapy, that excitement waned after Lilly acquired lebrikizumab. Beginning on or about August 19, 2020, and continuing through about February 16, 2023, Lilly oversaw a Phase 2 study of REZPEG in lupus (SLE) patients, titled "A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study of LY3471851 (NKTR-358) in Adults With Systemic Lupus Erythematosus" (study code: J1P-MC-KFAJ) (*i.e.*, the "Lupus Study" described herein). The Lupus Study was designed to evaluate REZPEG's efficacy and safety versus placebo in SLE patients.[29]

71. In 2019, Lilly initially planned the Phase 2 lupus study and knew that a significant patient pool was necessary to adequately power the study. Yet when Lilly performed an interim analysis of the Lupus Study, which showed REZPEG's promising efficacy against lupus, it failed to reasonably use the interim analysis to guide the Lupus Study's progress and correct course to ensure that the Lupus Study would be properly powered at its conclusion. During the course of the study, Lilly became aware that a significant number of patients had discontinued participating in the study, but failed to take commercially reasonable efforts to remedy the issue.

72. With the benefit of the information concerning the progress of the trial that was gained during this interim analysis, Lilly could have easily avoided underpowering in the study. Any number of commercially reasonable steps which Lilly could have taken, but failed to take, could have resulted in the Lupus Study being a success. By way of example, Lilly could have extended the Lupus Study long enough to enroll a sufficient number of study subjects and mitigate the known risks to having a properly powered study due to discontinuations and protocol deviations

[29] *A Study of LY3471851 in Adults With Systemic Lupus Erythematosus (SLE) (ISLAND-SLE)*, https://clinicaltrials.gov/study/NCT04433585.

in the study. Lilly also could have changed the primary endpoint to the same clinical endpoint adopted with the most recently approved drug treating lupus patients, as doing so represented the most recent market practice to show lupus efficacy. These and other reasonable steps, all of which Lilly failed to take, could have positioned REZPEG for success and moved it into Phase 3 studies as a lupus therapeutic.

73. Ultimately, because of Lilly's unreasonable lack of commitment and efforts to continue to enroll patients, the Lupus Study results were highly unlikely to achieve statistical significance for the original therapeutic endpoint (SLEDAI-2K). Lilly failed to correct course based on the interim data. Lilly simply sat by and took no meaningful action, and as a result the Lupus Study failed.[30]

74. Moreover, in analyzing data for subjects who completed 24 weeks on the Lupus Study, Lilly committed other serious errors, including omitting patients from the dataset. These patients included patients who responded to REZPEG treatment. Had Lilly correctly analyzed the available Lupus Study data (despite the underpowering of the Lupus Study based on a lower than expected number of evaluable patients), the results would have more strongly suggested REZPEG's potential therapeutic efficacy against lupus.

75. Lilly's conduct of the Lupus Study was at least grossly negligent, or an intentional breach of its obligations under the Agreement.

Termination of Nektar-Lilly Partnership

76. Under the Agreement, "Lilly may terminate this Agreement in its entirety or with respect to one or more particular Products or Compounds or with respect to one or more countries at any time without cause upon ninety (90) days' written Notice to Nektar." Agreement § 11.2. On information and belief, although Lilly did not wish to expeditiously continue developing REZPEG,

[30] *Nektar Therapeutics Announces Phase 2 Topline Data for Rezpegaldesleukin in Patients with Systemic Lupus Erythematosus* (Feb. 23, 2023), https://www.prnewswire.com/news-releases/nektar-therapeutics-announces-phase-2-topline-data-for-rezpegaldesleukin-in-patients-with-systemic-lupus-erythematosus-301754953.html.

it also did not want to voluntarily terminate the Agreement, as termination would allow Nektar to develop REZPEG on its own and compete with lebrikizumab.

77. Rather, Lilly hoped to continue to control REZPEG's development, which involved slow-rolling any new trial and designing it in a way to ensure REZPEG's failure, while accelerating lebrikizumab to market. Eventually, Lilly realized that its scheme could be exposed. On April 23, 2023, after Nektar asked for rights to REZPEG to be returned to Nektar, Lilly notified Nektar that Lilly was terminating the Agreement pursuant to section 11.2.

78. The day after the termination, April 24, 2023, Nektar requested all clinical data and databases associated with Lilly's REZPEG clinical studies, including materials used to generate external presentations. The Agreement requires that "[d]uring such ninety (90) day period [following Lilly's notice of termination], the Parties shall cooperate in the wind down of applicable activities under this Agreement in a commercially reasonable manner." Agreement § 11.2. The Agreement also requires Lilly to "reasonably cooperate with Nektar to facilitate a smooth, orderly and prompt transition (including during any notice period hereunder) of any ongoing Product development activities being conducted by or on behalf of Lilly or its Affiliates to Nektar" and to "promptly transfer or assign" to Nektar "any other materials or information necessary or useful (as such usefulness is reasonably determined by Nektar) for the continued development, manufacture and commercialization." *Id.* § 11.4(b)(ii). Nektar requires the foregoing materials in order to continue clinical development of REZPEG and to fulfill Nektar's regulatory obligations concerning REZPEG (*e.g.*, in the event of an audit by the FDA).

79. As of the filing of this Complaint, however, more than ninety (90) days after giving notice of terminating the Agreement, Lilly has not returned all materials requested by Nektar. Lilly has provided (either directly or through its subcontractors) raw data from Lilly's clinical studies, leading to the discovery of the wrongful acts, omissions, and errors described above. Although Nektar has pressed Lilly repeatedly for the transfer of all requested materials (and Nektar has confirmed that it will pay the related costs required under the Agreement), Lilly has failed to transfer all the requested materials.

80. Lilly has also indicated that it plans to "redact" or "scrub" information from some of the foregoing materials prior to providing these materials to Nektar. Any such redactions are improper and not provided for under the parties' Agreement, which states that Lilly is obligated to return all materials related to product development to Nektar upon a termination of the Agreement.

FIRST CAUSE OF ACTION

(Breach of Contract)

81. Plaintiff incorporates and realleges the allegations in all of the foregoing paragraphs as if fully set forth herein.

82. Lilly and Nektar formed a contract—the Agreement—on or about July 23, 2017.

83. Under the Agreement, the parties had certain rights and obligations.

84. Among other things, the Agreement required Nektar to grant an exclusive license to Lilly to develop, register, make and have made, use, sell, have sold, offer for sale, import, and export, the compound drugs and products identified in the Agreement (specifically, REZPEG). Agreement § 2.1. Nektar performed this and its other obligations under the Agreement.

85. Pursuant to the parties' Agreement, Lilly undertook exclusive responsibility for the proper conduct of multiple clinical studies of REZPEG, including the Eczema Study, the Psoriasis Study, and the Lupus Study described above. *Id.* § 4.5 ("Product Development by Lilly"); *id*. § 4.9 (Lilly was obligated to develop and receive regulatory approval for at least one product). Nektar did not control or have the right to control the design or conduct of any of the foregoing clinical studies. Indeed, prior to termination of the Agreement, Nektar did not have access to the raw data from any of the foregoing clinical studies.

86. The Agreement required Lilly to use commercially reasonable efforts in designing and conducting these studies, in developing REZPEG, and in bringing it to market. *Id.* § 4.1 (Lilly will use "Commercially Reasonable Efforts" in performing its responsibilities in the Product Development Plan); *id.* § 4.5 ("Lilly shall use Commercially Reasonable Efforts to conduct all Product development activities"); *id.* § 4.9 ("Lilly will use Commercially Reasonable Efforts to develop, receive Regulatory Approval for, market and sell at least one Product in the Field in the Major Markets").

87. The Agreement also required Lilly to "act in good faith" when performing its "assigned tasks and responsibilities" associated with the development of REZPEG. *Id.* § 4.1 (Nektar and Lilly would each "act in good faith . . . to perform their assigned tasks and responsibilities as described in the Product Development Plan").

88. The Agreement imposed liability on each party "for any act or omission of its subcontractor." *Id.* § 4.10.

89. Lilly breached its obligations under the Agreement in many specific ways, including by the conduct outlined herein and, in general, deprioritizing and undermining REZPEG. Among other things, Lilly did not act in good faith or use commercially reasonable efforts in developing REZPEG, and in all instances Lilly was either grossly negligent or committed intentional misconduct.

90. As a direct and proximate result of Lilly's breaches as described herein, Nektar has been damaged, including by delaying regulatory approvals for and commercialization of REZPEG, in an amount to be proven at trial. Examples of Lilly's contractual breaches include, but are not limited to, the following:

Lilly Breached the Agreement by Using the Botched Math in the Eczema and Psoriasis Studies

91. Lilly breached the Agreement by using the Botched Math, as discussed above.

92. The Agreement defined Good Research Practices (Agreement, Art. I) by reference to Lilly's quality standards, which Lilly committed to follow and which were attached as Schedule 4.8 Part A to the Agreement. This Schedule 4.8, Part A, represented that personnel acting on behalf of Lilly would be "qualified and can perform Study tasks to meet expectations[.]" The same Schedule 4.8, Part A, represented that data would be "managed to ensure accuracy, completeness and retrievability." The same Schedule 4.8, Part A, represented that "All data included in reports ***must*** be reviewed to ensure that the reports accurately reflect the data" (emphasis added).

93. Lilly's failure to calculate the EASI and PASI correctly, and to properly supervise any such work performed by its subcontractor(s), was grossly negligent or intentional. The EASI and PASI are each simple metrics and are familiar to all practitioners and clinicians who study

eczema and psoriasis. The serious error in the Botched Math would have been immediately apparent to any person with even basic familiarity with the EASI or PASI. Lilly compounded its breach by thereafter publicizing the Botched Interim Eczema Results at least in the False Eczema Publication and the False Psoriasis Publication. This resulted in an unjustly negative perception of REZPEG by the market, customers and consumers and harm to Nektar.

94. Lilly's failure to direct, supervise, and review or validate the data analysis properly was a breach of its Good Research Practices, as outlined in the Agreement. Lilly's failure to direct, supervise, and review the data analysis properly was also a breach of its obligation to use commercially reasonable efforts, because the expertise and resources devoted to any comparable pharmaceutical product would be sufficient at least to analyze data correctly. And Lilly's failure to direct, supervise, and review the data analysis properly was a failure to act in good faith because it deprived Nektar of the benefits of the Agreement, including developing REZPEG to approval and manufacture.

Lilly's Eczema Phase 2 Study Design Breached the Agreement

95. Lilly breached the Agreement in developing the Eczema Phase 2 Study Plan, as discussed above.

96. Lilly proposed using [redacted]nterim analyses of study data in the Eczema Phase 2 Study Plan. As set forth above, clinical studies do not typically use [redacted]nterim analyses of study data.

97. Lilly's design of the Eczema Phase 2 Study Plan was intended to increase the probability of early termination of REZPEG development—an unreasonable design proposal and one not made in good faith as required under the Agreement.

98. REZPEG's delayed entry into Phase 2 eczema clinical trials is a direct consequence of Lilly failing to use commercially reasonable efforts to design the Eczema Phase 2 Study Plan. These delays have harmed Nektar because they have delayed approval and sales of REZPEG.

99. REZPEG's delayed entry into Phase 2 eczema clinical trials also significantly compromises Nektar's critical first-mover advantage in the field of interleukin-2 therapies for eczema treatment. As set forth above, multiple companies have begun developing interleukin-2-based therapies for eczema.

100. Lilly's failure to properly develop the Eczema Phase 2 Study Plan was a breach of its obligation to use commercially reasonable efforts, because the Eczema Phase 2 Study Plan departed significantly from the scrutiny applied to comparable pharmaceutical products. Lilly's failure to properly develop the Eczema Phase 2 Study Plan was a failure to act in good faith because it deprived Nektar of the benefits of the Agreement, including developing REZPEG to approval and manufacture.

Lilly's Conduct of the Lupus Study Breached the Agreement

101. Lilly breached the Agreement in conducting the Lupus Study, as discussed above.

102. Lilly failed to use commercially reasonable efforts to ensure the proper conduct of the Lupus Study. As set forth above, by way of example, when Lilly performed an interim analysis of the Lupus Study, which showed REZPEG's promising efficacy against lupus, it failed to reasonably use the interim analysis to guide the Lupus Study's progress and correct course to ensure that the Lupus Study would be properly powered at its conclusion. Moreover, as set forth above, in analyzing data for subjects who completed 24 weeks on the Lupus Study, Lilly committed other serious errors, including omitting patients from the dataset.

103. Lilly's conduct of the Lupus Study was at least grossly negligent, or an intentional breach of its obligations under the Agreement.

104. Lilly's failure to conduct the Lupus Study correctly was a breach of its obligation to use commercially reasonable efforts, because the Lupus Study departed significantly from the standards applicable to trials for comparable pharmaceutical products. Lilly's failure to properly develop the Lupus Study was a failure to act in good faith because it deprived Nektar of the benefits of the Agreement, including developing REZPEG to approval and manufacture.

Lilly's Failure to Return Materials Breached the Agreement

105. The Agreement requires "Lilly shall reasonably cooperate with Nektar to facilitate a smooth, orderly and prompt transition (including during any notice period hereunder) of any ongoing Product development activities being conducted by or on behalf of Lilly or its Affiliates to Nektar or its designee(s)." *Id.* § 11.4(b)(ii). It further requires that Lilly "shall use Commercially Reasonable Efforts, at Nektar's sole cost and expense, with respect to any such ongoing Product

development activities to promptly transfer," among other things, "any other materials or information necessary or useful (as such usefulness is reasonably determined by Nektar) for the continued development, manufacture and commercialization of" REZPEG. *Id.*

106. More than a year after Lilly sent Nektar notice of termination of the Agreement, however, Lilly has still not returned all materials requested by Nektar.

107. Lilly's obligations under section 11.4(b) of the Agreement survive the termination of the Agreement. *Id.* § 11.6.

108. The foregoing actions by Lilly constitute a breach of at least section 11.4(b) of the Agreement and other provisions noted above.

SECOND CAUSE OF ACTION

(Breach of the Implied Covenant of Good Faith and Fair Dealing)

109. Plaintiff incorporates and realleges the allegations in all of the foregoing paragraphs as if fully set forth herein.

110. Lilly and Nektar entered into the Agreement on or about July 23, 2017. Under the Agreement, the parties had certain rights and obligations. Nektar performed its obligations under the Agreement. Lilly breached its obligations under the Agreement.

111. The Agreement selected application of New York law to govern and interpret the Agreement. Agreement § 12.12. A covenant of good faith and fair dealing is implied in all contracts governed by New York law.

112. Lilly breached the Agreement by acting in a manner that, although arguably not expressly forbidden by any contractual provision, deprived Nektar of the right to receive the benefits under the Agreement.

113. Lilly took actions intended to delay or prohibit the approval of REZPEG, including as detailed above. The overall purpose of these delays and instances of misconduct was to delay regulatory approval or to ensure that REZPEG would fail, thereby allowing Lilly to avoid making the anticipated Milestone Payments and royalty payments that Lilly would owe to Nektar as REZPEG progressed to approval and marketing, and to provide Lilly with an unfair and significant head start for its own competing drug candidate.

114. There was an implied covenant in the Agreement obliging Lilly not to thwart the purposes of the Agreement nor to deny Nektar the fruits of the bargain. Lilly was motivated to thwart REZPEG's development and to delay its approval and marketing in part because Lilly owed certain Milestone Payments and other financial obligations under the Agreement. Agreement § 6.2. These Milestone Payments were worth hundreds of millions of dollars as REZPEG progressed towards approval. By its misconduct, Lilly acted with the intention of depriving Nektar of the benefit of these financial rewards. As an example, by its improper conduct, Lilly has successfully avoided making *any* Milestone Payments under the Agreement. Lilly was also motivated to delay or thwart the development of REZPEG in part because Lilly purchased a competing drug, lebrikizumab, after it entered into the Agreement with Nektar.

115. In addition, Lilly's termination of the Agreement was a violation of the implied covenant of good faith and fair dealing. Although the Agreement incorporated a mutual right for both parties to terminate the Agreement under defined circumstances, the exercise of that right was bound by the implied covenant. Lilly was obligated always to act in good faith and always to engage in fair dealing. Lilly did not terminate in good faith because Lilly's termination arose not out of any organic failure on the part of REZPEG, nor as a result of any financial constraint at Lilly, but rather because Lilly found an improper road around the bargain it had struck. That bargain was to develop REZPEG as a therapeutic. Rather than try to achieve that purpose, Lilly instead purchased a competing drug and obstructed, rather than encouraged, the development of REZPEG. Lilly prioritized the development of its own drug over REZPEG and injured REZPEG by delaying its development and tarnishing its prospects by publishing incorrect data about its efficacy in clinical trials, and by other grossly negligent and intentional misconduct, as detailed above. Lilly then terminated the Agreement in bad faith, abandoning the continued development of REZPEG, and returning to Nektar a tarnished asset.

116. Lilly's misconduct was in all instances either grossly negligent or intentional and had the effect of denying Nektar the benefits under the Agreement, which thereby breached the implied covenant of good faith and fair dealing implied in the Agreement.

117. As a direct and proximate result of Lilly's breaches as described herein, Nektar has been damaged, including by not receiving the Milestone Payments and royalty payments, and by Lilly not continuing to spearhead and fund REZPEG's product development, in an amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Nektar respectfully requests judgment as follows:

1. That judgment be entered in favor of Nektar and against Lilly;
2. For compensatory damages in an amount to be proven at trial;
3. For enforcement of the Agreement and payment of all sums owed to Plaintiff in connection with the Agreement;
4. That Nektar be awarded pre- and post-judgment interest;
5. That Nektar be awarded its costs and expenses in connection with this action, including attorneys' fees and expenses;
6. That an injunction issue ordering Lilly to return all requested materials it has not yet provided to Nektar as required under sections 11.2 and 11.4(b)(ii) of the Agreement; and
7. That the Court award Nektar such other and further relief as may be just and proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Nektar hereby demands trial by jury of all issues properly triable thereby.

DATED: May 3, 2024

Respectfully submitted,

QUINN EMANUEL URQUHART & SULLIVAN, LLP

By */s/ Yury Kapgan*
Yury Kapgan
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